

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

**NOVARTIS PHARMACEUTICALS
CORPORATION,**

Plaintiff,

v.

Case No. 2:24-cv-04131-MDH

**ANDREW BAILEY, in his official capacity as
ATTORNEY GENERAL OF THE STATE OF
MISSOURI; JAMES L. GRAY, in his official
capacity as President of the Missouri Board of
Pharmacy; CHRISTAN S. TADRUS, in his
official capacity as Vice-President of the
Missouri Board of Pharmacy; and DOUGLAS
R. LANG, ANITA K. PARRAN, COLBY
GROVE, TAMMY THOMPSON, and DARREN
HARRIS, in their official capacities as members
of the Missouri Board of Pharmacy,**

Defendants.

v.

**MISSOURI HOSPITAL ASSOCIATION,
And MISSOURI PRIMARY CARE
ASSOCIATION,**

Intervenors

ORDER

Before the Court are State Defendant's Motion to Dismiss for Failure to State a Claim. (Doc. 31) and Intervenor's Motion to Dismiss for Failure to State a Claim. (Doc. 63). Plaintiff has filed its suggestions in opposition. (Docs. 35 and 67). Both State Defendants and Intervenor Defendants (collectively "Defendants") have filed their replies. (Docs. 49 and 70). The matter is

now ripe for adjudication. For reasons herein, Defendants' Motions are **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

This case arises out of Senate Bill ("S.B.") 751 which created protections to the delivery of 340B drugs to contract pharmacies on behalf of "covered entities". Section 340B incentivizes pharmaceutical manufacturers to provide qualified health care providers, referred to as "covered entities," with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. Covered entities have contracted with outside pharmacies or "contract pharmacies," for the distribution and dispensation of 340B drugs. S.B. 751 protects hospitals, federal qualified health centers ("FQHC"), and their patients from drug manufacturers' restrictions on the number of contract pharmacies a hospital or FQHC can use and still receive discount pricing under 340B plan. Plaintiff is a pharmaceutical corporation organized in Delaware with its principal place of business in New Jersey. Defendants are all residents of Missouri that are responsible for administering and enforcing the provisions of S.B. 751. Intervenor Missouri Hospital Association and Missouri Primary Care Association are Missouri, not-for-profit member organizations.

Plaintiff alleges three Counts seeking declaratory relief that S.B. 751 is unconstitutional and injunctive relief barring enforcement of S.B. 751. Count I alleges S.B. 751 is preempted by federal patent and drug exclusivity laws under the Supremacy Clause. Count II alleges S.B. 751 is preempted by federal 340B law under the Supremacy Clause and Count III alleges S.B. 751 violates the dormant Commerce Clause. Defendants argue S.B. 751 is not preempted by the federal patent and drug exclusivity laws because S.B. 751 does not adjust 340B drug prices. Defendants next argue S.B. 751 is not preempted by the federal 340B law based on Eighth Circuit precedent.

Finally, Defendants assert that the dormant Commerce Clause is not implicated because S.B. 751 is not discriminatory nor does its burden on interstate commerce exceed the local benefits.

STANDARD OF REVIEW

A complaint must contain factual allegations that, when accepted as true, are sufficient to state a claim of relief that is plausible on its face. *Zutz v. Nelson*, 601 F.3d 842, 848 (8th Cir. 2010) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The Court “must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party.” *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005) (internal citations omitted). The complaint’s factual allegations must be sufficient to “raise a right to relief above the speculative level,” and the motion to dismiss must be granted if the complaint does not contain “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 545 (2007). Further, “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. *Ashcroft*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

ANALYSIS

I. Count I – Preemption by Federal Patent and Drug Exclusivity Laws

Count I seeks declaratory and injunctive relief claiming S.B. 751 is preempted by the federal patent and drug exclusivity laws under the Supremacy Clause of the United States Constitution. Specifically, the federal patent and drug exclusivity laws conflict preempt S.B. 751. Defendants argue that Count I should be dismissed because federal marketing exclusivity periods do not conflict preempt S.B. 751 as S.B. 751 does not adjust prices at which Plaintiff sells 340B drugs.

“Article VI of the Constitution provides that the laws of the United States ‘shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.’” U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are “without effect.” *Cipollone v. Liggett grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, L.Ed.2d 407 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015). Congress may impliedly preempt state law “either through ‘field’ preemption or ‘conflict’ preemption.” *Id.* Conflict preemption exists where ‘compliance with both state and federal law is impossible,’ or where ‘the state law stands as an obstacle to the accomplishment and execution of the full purposes and objections of Congress.’” *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989)).

Plaintiff argues that S.B. 751 reduces the value of the exclusivity periods and patent terms that the Food, Drug, and Cosmetic Act and federal patent laws guarantee to qualifying drug manufacturers. (Complaint ¶ 113). Plaintiff alleges that the Missouri Legislature defined a “340B drug” as a drug sold at a 340B discount. Plaintiff further alleges the Missouri statute requires manufacturers like Plaintiff to provide the 340B discount on transactions that involve contract pharmacies. (Complaint ¶¶ 57-59). Plaintiff states this is evident that S.B. 751 is not about the delivery of 340B drugs but about the pricing of the drugs. (Complaint ¶ 60). Plaintiff further alleges that state laws that cap or fix the prices at which patented drugs may be sold are preempted by federal patent law because they attempt to re-balance the carefully constructed federal statutory scheme that allocates rewards and incentives to manufacturers. (Complaint ¶ 73).

Taking the allegations as true for the purpose of a motion to dismiss, Plaintiff has failed to raise a right to relief above a speculative level. The Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v. McClain* reviewed a similar Arkansas statute where the plaintiff in that case argued an analogous Arkansas law set a price cap and thus was conflict preempted by a different federal law. The Eighth Circuit ruled the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies nor does the state statute set or enforce discount pricing. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136, 1145 (8th Cir. 2024), *cert. denied*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024). S.B. 751 likewise does the same thing as the Arkansas statute and does not require manufacturers to extend the federal 340B discount to contract pharmacies. S.B. 751 which revised Mo. Rev. Stat. § 376.414 states:

A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider, *shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity* unless such receipt is prohibited by the United States Department of Health and Human Services. A wholesale drug distributor, as defined in section 338.330, shall not be considered an agent or affiliate for purposes of this subsection.

Mo. Rev. Stat. § 376.414.2. (emphasis added). The Statute by its plain terms only places restrictions on what pharmaceutical manufacturers or third-party logistic providers can restrict or prohibit regarding the acquisition or delivery of 340B drug to a contract pharmacy on a covered entity's behalf. The statute does not make any mention of exclusivity periods, patent terms, or even pricing discounts.

The 340B Program has specific enforcement measures that safeguards the prices at which manufacturers can sell their patented drug while also complying with the provisions of the 340B

program. The discounted price or “ceiling price” a drug manufacturer may charge in the 340B program is determined by statutory formula. 42 U.S.C. §§ 256b(a)(2), 1396r-8(c). Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug. *Id.* § 256b(a)(5)(A)-(B). Additionally, covered entities may not engage in diversion of covered outpatient drugs through “resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the [covered] entity.” *Id.* § 256b(a)(5)(b).

Taking Plaintiff’s allegation as true for the purposes of a motion to dismiss it has failed to show a right to relief above a speculative level. Covered entities cannot prescribe discounted 340B drugs except to those who qualify under the program. Both the plain language of the statute as well as precedent within the Eighth Circuit has established that statutes akin to S.B. 751 do not directly regulate the pricing of 340B drugs as regulation of pricing is determined by the federal 340B statute. Further, S.B. 751 does not require manufacturers to give the 340B discount to contract pharmacies. As such S.B. 751 does not conflict preempt the Federal Patent and Drug Exclusivity Laws under the Supremacy Clause. For the reasons stated, Defendants’ Motion to Dismiss Count I is **GRANTED**.

II. Count II – Preemption by the Federal 340B Law

Count II seeks declaratory and injunctive relief claiming S.B. 751 is preempted by the Federal 340B Law under the Supremacy Clause. Specifically, Plaintiff alleges S.B. 751 is both field preempted and conflict preempted by the federal 340B law. Defendants argue that Count II should be dismissed because the Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v.*

McClain, 95 F.4th 1136 (8th Cir. 2024) has ruled a similar Arkansas statute was not field preempted or conflict preempted by federal 340B law.

A. Field Preemption

When a federal regulatory scheme occupies the field because of its pervasive nature, leaving no room for state action, field preemption applies. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). Field preemption also applies when Congress “intend[s] ‘to foreclose any state regulation in the [regulated] are,’ irrespective of whether state law is consistent or inconsistent with ‘federal standards.’” *Oneok, Inc.*, 575 U.S. at 377, 135 S.Ct. 1591 (quoting *Arizona v. United States*, 567 U.S. 387, 401, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012)). Congress’s intent to preempt a field “can be inferred from a framework of regulation ‘so pervasive ... that Congress left no room for the States to supplement it’ or a ‘federal interest ... so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.’” *Arizona*, 567 U.S. at 399, 132 S.Ct. 2492 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

Under Eighth Circuit precedent the 340B program is not “so pervasive ... that Congress left no room for the States to supplement it. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136 (8th Cir. 2024) at 1144 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). The Eighth Circuit reasoned that pharmacies have always been an essential part of the 340B program and Congress’s decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field. *Id.* The practice of pharmacy is an area traditionally left to state regulation and that the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to stand by both concept and to

tolerate whatever tension there [is] between them.” *Id.* Further, the Eighth Circuit analyzed the difference between a state statute that ensures an oversight and enforcement scheme in promoting its protections for covered entities to distribute 340B compared to the federal 340B Program and its means for enforcement of discount prices. *Id.* The Eighth Circuit found that a statute which establishes enforcement for the distribution of 340B drugs and the federal 340B law’s enforcement scheme address two completely different issues and thus Congress did not intent to preempt the field with its 340B legislation.

Taking Plaintiff’s allegation as true for the purpose of a motion to dismiss, Plaintiff fails to state a claim upon which relief can be granted given this circuit’s precedent in *McClain*. For the reasons stated herein, Defendants’ Motion to Dismiss Count II as it relates to field preemption is **GRANTED**.

B. Conflict Preemption

“Where state and federal law ‘directly conflict,’ state law must give way. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011). Obstacle preemption exists where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000). What qualifies as “a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.” *Id.* “If the purpose of the act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state law must yield to the regulation of Congress within the sphere of its delegated power.” *Id.*

Plaintiff argues that SB 751 imposes a substantial obstacle to the achievement of federal purpose and objections. Specifically, SB 751 requires manufacturers to provide the federal 340B

discount on an unlimited number of transactions involving contract pharmacies. (Complaint ¶ 118). A similar argument was made in *McClain*. The Eighth Circuit ruled the Arkansas law did not require manufactures to provide 340B pricing discounts to contract pharmacies nor does the state statute set or enforce discount pricing revealing create no obstacle to the enforce of the 340B program. *McClain at 1145*. Additionally, the Arkansas law's enforcement scheme is in place to deter pharmaceutical manufactures from interfering with a covered entity's contact pharmacy arrangements and again creates no obstacle for pharmaceutical manufactures to comply with both the state statute and Section 340B. *Id.*

Here, S.B. 751 does the exact same. S.B. 751 does not require manufacturers to extend the federal 340B discount to contract pharmacies, it just restricts pharmaceutical companies from infringing on the distribution and delivery of 340B drugs bought by covered entitles utilizing the 340B program. S.B. 751 does not set or enforce discount pricing but protects covered entities use of contract pharmacies. As such, there is no obstacle to the enforcement of the 340B program. Likewise, S.B. 751 creates an enforcement scheme that makes any violation of a pharmaceutical manufacturer or third-party logistics provider an unlawful practice. Mo. Rev. Stat. § 376.414.3. It details the appropriate statutes should a violation happen to obtain compliance through monetary penalties and equitable relief.¹ *Id.* Consistent with the precedent set by the Eighth Circuit, Plaintiff has failed to allege a claim upon which relief can be granted. For the reasons stated, Defendants' Motion to Dismiss Count II as it relates to obstacle preemption is **GRANTED**. Count II is **DISMISSED** in its entirety.

III. Count III – Violation of the Dormant Commerce Clause

¹ Mo. Rev. Stat. § 376.414.3 provides any act prohibited by subsection shall constitute an unlawful practice which any action may be authorized under Mo. Rev. Stat. §§ 407.010-407.130. Particularly relevant is Mo. Rev. Stat. § 407.100 which details remedies from the court such as restitution, civil penalties of not more than \$1000.00 per violation, injunctions, temporary restraining orders, and other remedies.

Count III seeks declaratory and injunctive relief that S.B. 751 is unconstitutional as it violates the Commerce Clause of the United States Constitution. (Complaint ¶ 122). The Constitution vests Congress with the power to “regulate Commerce...among the several States.” U.S. Const. art. I, § 8, cl. 3. The Supreme Court has held the Commerce Clause gives Congress exclusive legislative jurisdiction over interstate commerce, meaning states may not enact laws that “unduly restrict interstate commerce.” *Styczinski v. Arnold*, 46 F.4th 907, 912 (8th Cir. 2022) (quoting *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, --- U.S. ----, 139 S.Ct. 2449, 2459, 204 L.Ed. 2d 801 (2019)). This restriction is commonly referred to as the dormant Commerce Clause. *Id.* A state statute violates the dormant Commerce Clause if it “(1) ‘clearly discriminates against interstate commerce in favor of in-state commerce,’ (2) ‘imposes a burden on interstate commerce that outweighs any benefits received,’ or (3) ‘has the practical effect of extraterritorial control on interstate commerce.’” *Grand River Enters. Six Nations, Ltd. V. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009). Plaintiff alleges S.B. 751 violates the dormant Commerce Clause in all three respects.

A. Discrimination on Interstate Commerce

Plaintiff alleges S.B. 751 privileges in-state pharmacies while significantly burdening out-of-state manufacturers like Plaintiff. (Complaint ¶ 124). Defendants argue this is the wrong comparison under a dormant Commerce Clause analysis and that the correct analysis is whether S.B. 751 discriminates against out-of-state drug manufacturers in favor of in-state drug manufacturers. Defendants claim that S.B. 751 treats in-state manufacturers the same as out-of-state manufacturers, therefore there is no dormant Commerce Clause violation under the discriminatory intent or effect theory.

When considering a dormant Commerce Clause violation, we must first determine “whether the challenged law discriminates against interstate commerce.” *Jones v. Gale*, 470 F.3d 1261, 1267 (8th Cir. 2006). A state statute discriminates against interstate commerce if it accords “differential treatment of in-state and out-of-state economic interest that benefits the former and burdens the latter.” *Id.* A law can discriminate in three ways: 1) it can discriminate on its face; 2) it can have a discriminatory purpose; or 3) it can have a discriminatory effect. *Id.* The dormant Commerce Clause is only implicated when the discrimination is between “substantially similar entities.” *MDKC, LLC v. City of Kansas City*, No. 4:23-CV-00395-DKG, 2023 WL 6406403 at *7 (W.D. Mo. Oct. 2, 2023) (quoting *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 342, 128 S. Ct. 1801, 1811, 170 L. Ed. 2d 685 (2008)).

While Defendant cites many cases that show a similar comparison of comparing the same industry and comparing the effects of the in-state industry compared to the out-of-state industry for purposes of the dormant Commerce Clause analysis, the Court finds this is not dispositive. The Court has found no case law that specifies that a dormant Commerce Clause analysis must be predicated on comparing the same industry and reviewing the effects simply from an in-state or out-of-state vantage point. A fundamental element of dormant Commerce Clause jurisprudence is the principle that “any notion of discrimination assumes a comparison of substantially similar entities.” *Dep’t of Revenue of Ky. v. Davis*, U.S. 328, 342 (2008). Therefore, the analysis must focus on substantially similar entities.

Taking as true the allegations for the purpose of a motion to dismiss, Plaintiff has raised the right of relief above a speculative level. Plaintiff claims the goal of S.B. 751 is to protect in-state industries, such as hospitals and pharmacies, by forcing out-of-state manufacturers to give them a steep discount. (Complaint ¶ 97). Plaintiff further claims Missouri’s law advantages in-

state interests by making it unlawful for out-of-state firms to refuse extending through Missouri pharmacies a below-market bargain, or to refuse to bargain at all, it violates the dormant Commerce Clause. *Id.* This is sufficient at this stage of the litigation to warrant further consideration. For the reasons stated, Defendants’ Motion to Dismiss on Count III – Discrimination on Interstate Commerce is **DENIED**.

B. Burden on Interstate Commerce

Defendants first argue that *Nat’l Pork Producers Council v. Ross* eliminated the balancing test established under *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 90 S.Ct. 844, 25 L.Ed.2d 174 (1970) (“Pike Test”). The Pike Test states state legislation is valid if “the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental. *Id.* at 142. The statute will be upheld “unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” *Id.*

Nat’l Pork Producers Council v. Ross does not eliminate the Pike Test, rather it declined to extend Pike past what prior case precedent held.

While Pike has traditionally served as another way to test for purposeful discrimination against out-of-state economic interest, and while some of our cases associated with that line have expressed special concern with certain state regulation of the instrumentalities of interstate transportation petitioners would have us retool Pike for a much more ambitious project. They urge us to read Pike as authorizing judges to strike down duly enacted state laws regulating the in-state sale of ordinary consumer goods (like pork) based on nothing more than their own assessment of the relevant law’s “costs” and “benefits.” That we can hardly do.

Nat’l Pork Producers Council v. Ross, 598 U.S. 356, 380, 143 S. Ct. 1142, 1159, 215 L. Ed. 2d 336 (2023) (citations omitted). Additionally, courts within the district continue to utilize the Pike Test post *Nat’l Pork Producers Council v. Ross*. See *MDKC, LLC v. City of Kansas City*, No. 4:23-CV-00395-DKG, 2023 WL 6406403 (W.D. Mo. Oct. 2, 2023). As such, the Pike Test has not been

eliminated by *Nat'l Pork Producers Council v. Ross* and is still good law today within the district and the Eighth Circuit.

Defendant next argues that even if the Pike Test applies, Plaintiff still cannot state a claim because it has not pleaded facts showing that S.B. 751 imposes a “substantial burden” on interstate commerce. The Court must analyze whether the burden imposed by the Statute is excessive compared to the benefits. *Turtle Island Foods, SPC v. Thompson*, 725 F. Supp. 3d 963, 977 (W.D. Mo. 2024). The extent of the burden that will be tolerated will depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.” *Id.* (quoting *Ass’n to Pres. & Protect Loc. Livelihoods v. Town of Bar Harbor*, 721 F. Supp. 3d 56, 95 (D. Me. 2024)). But even so, “preventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of ‘extreme delicacy’, something courts should do only ‘where the infraction is clear.’” *Id.*

Plaintiff has alleged four burdens within its Complaint. Plaintiff first alleges that the bargaining power favors in-state pharmacies and covered entities at the expense of out-of-state drug manufacturers. (Complaint ¶ 99). Second, Manufacturers will have to contend with a patchwork of state laws with different terms and different requirements, each purporting to regulate transactions that are primarily nationwide in nature. (Complaint ¶ 100). Third, it will be virtually impossible for manufacturers and wholesalers to map multiple overlapping and insistent state laws onto nationwide contracts without creating conflicts and forcing violations of competing state law. (Complaint ¶ 101). Fourth, as more state laws like S.B. 751 become prevalent in different states the burden on interstate commerce will snowball. (Complaint ¶¶ 102).

Taking Plaintiff's factual allegations as true for the purposes of a motion to dismiss, Plaintiff has raised the right of relief above a speculative level. Plaintiff sufficiently alleges four burdens that would result in a significant burden upon interstate commerce for Plaintiff individually and those similarly situated. While there are local benefits that may warrant further scrutiny of this claim, at this state of the litigation Plaintiff's allegations are sufficient. For the reasons stated, Defendants' Motion to Dismiss on Count III – Burden on Interstate Commerce is **DENIED**.

C. Extraterritorial Control on Interstate Commerce

Defendants argue that S.B. 751 does not apply extraterritorially and even so S.B. 751 does not directly regulate transactions taking place wholly outside the state and involving individuals having no connection with the state. Plaintiff asserts that the practical discriminatory effect of Missouri's law is to directly regulate wholly out-of-state transactions between manufacturers and other private entities.

The Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the state. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989). A statute directly controlling wholly out-of-state commerce "is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* However, there is no per se rule under the dormant Commerce Clause forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State, when those laws do not purposely discriminate against out-of-state economic interests. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 143 S. Ct. 1142, 1159, 215 L. Ed. 2d 336 (2023).

For the purposes of a motion to dismiss, Plaintiff has alleged facts that raise a right to relieve above a speculative level. Plaintiff alleges that drug manufacturers typically sell its products to national wholesalers and distributors located around the country. (Complaint ¶ 96) Those wholesalers then sell the products to national chain pharmacies which in turn will be dispensed by contract pharmacies to patients located in Missouri. *Id.* The 340B discount then travels back in the opposite direction when covered entities file a chargeback with the wholesalers who file a retroactive request for payment with manufacturers. *Id.* Plaintiff alleges it is that last transaction which runs afoul of the extraterritorial concerns and which S.B. 751 compels manufacturers and wholesalers to act in accordance with Missouri law outside Missouri. *Id.* These allegations are sufficient at this stage of the litigation to continue. For the reasons stated, Defendants' Motion to Dismiss on Count III – Extraterritorial Control on Interstate Commerce is **DENIED**.

CONCLUSION

For reasons herein, Defendants' Motion is Dismiss is **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motion to Dismiss Count I is **GRANTED**. Defendants' Motion to Dismiss Count II is **GRANTED** and Defendants' Motion to Dismiss Count III is **DENIED**.

IT IS SO ORDERED.

DATED: February 13, 2025

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE